EXHIBIT B

DMS

(1)

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ICN PHARMACEUTICALS, INC., Plaintiff, vs. TEVA PHARMACEUTICALS USA, INC., Defendant.	CIVIL ACTION No. 02cv600 FILED 2002 JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT AND INTENTIONAL INTERFERENCE WITH PROSPECTIVE CONTRACTUAL RELATIONS

PARTIES

1 Plaintiff, ICN PHARMACEUTICALS, INC. ("ICN"), is a corporation organized under the laws of the State of Delaware, with its principal place of business at 3300 Hyland Avenue, Costa Mesa, California 92626.

2. Defendant, TEVA PHARMACEUTICALS USA, INC. ("TEVA"), is, upon information and belief, a corporation organized under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

3. TEVA is, upon information and belief, doing business in California

JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, and 1367, and 35 U.S.C. §§ 101, et seq., and because the action set forth herein arises under the Act of Congress relating to patents.

5. Upon information and belief, TEVA is subject to personal jurisdiction in this District because it: (1) regularly solicits business in this District by making pharmaceutical products in, and shipping pharmaceutical products into, this District; (2) regularly distributes pharmaceutical products in this District, (3) offers to sell, is selling, or is causing others to use pharmaceutical products in this District; (4) derives substantial revenue from sales and distribution of pharmaceutical products in this District; and (5) has otherwise engaged in a persistent course of conduct in this District. Defendant TEVA derives substantial revenue from interstate or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of California and this Judicial District. Defendant TEVA has committed, and unless enjoined will continue to commit, tortious acts outside of the State of California that TEVA expects or should reasonably expect to have consequences in the State of California.

6 Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

COUNT ONE

PATENT INFRINGEMENT

7 ICN is the lawful owner by assignment of all right, title and interest in and to the following United States patents, including all right to sue and to recover for past infringement thereof:

(a) United States Patent No. 5,767,097 ("'097"), duly and legally issued on June 16, 1998, entitled "SPECIFIC MODULATION OF TH1/TH2 CYTOKINE EXPRESSION BY RIBAVIRIN IN ACTIVATED T-LYMPHOCYTES";

(b) United States Patent No. 6,063,772 ("'772"), duly and legally issued on May 16, 2000, entitled "SPECIFIC MODULATION OF TH1/TH2 CYTOKINE EXPRESSION BY RIBAVIRIN IN ACTIVATED T-LYMPHOCYTES"; and

(c) United States Patent No. 6,150,337 ("'337"), duly and legally issued on November 21, 2000, entitled "SPECIFIC MODULATION OF TH1/TH2 CYTOKINE EXPRESSION BY RIBAVIRIN IN ACTIVATED T-LYMPHOCYTES."

8. A true and correct copy of each of the patents mentioned above is attached hereto as Exhibits A, B and C and are herein collectively referred to as "INTELLECTUAL PROPERTY."

9 The 5,767,097; 6,063,772; and 6,150,337 patents are directed generally to novel uses of ribavirin

10. Plaintiff, ICN, markets and sells ribavirin in the United States in cooperation with its licensee, Schering Plough Corporation

11 Upon information and belief, TEVA submitted to the Federal Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA"), No 76-277, under §505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)) to obtain approval to engage in the commercial manufacture, use or sale of ribavirin 200 mg. capsules, a generic version of plaintiffs' ribavirin, before the expiration date(s) of the INTELLECTUAL PROPERTY.

12 Upon information and belief, TEVA's submission of ANDA No. 76-277 was an act of infringement of the INTELLECTUAL PROPERTY under the United States Patent Law, 35 U S C §271(e)(2)(A).

13. TEVA sent a "PATENT CERTIFICATION NOTICE" [No. 76-277] ("NOTICE") to Plaintiff. TEVA's Notice is dated January 18, 2002. Plaintiff received TEVA's Notice on or about January 28, 2002. A true and correct copy of the letter prepared by TEVA and received by Plaintiff is attached hereto as Exhibit D.

1. Upon information and belief, TEVA has actual knowledge of the existence of Patents 5,767,097, 6,063,772; and 6,150,337 by virtue of prior information available in the industry at large, by virtue of Patents 5,767,097; 6,063,772; and 6,150,337 having been listed on the FDA Orange Book for Rebetron™ Combination, and with respect to 5,767,097 and 6,063,772 by virtue of the January 18, 2002 Notice sent to ICN mentioning same.

15. TEVA's acts of infringement, including inducing infringement, set forth with respect to TEVA's ribavirin 200 mg. capsules, will cause Plaintiff irreparable harm for which it has no adequate remedy at law, including irreparable harm within the State of California and this Judicial District, and will continue unless preliminarily and permanently enjoined by this Court.

16. Upon information and belief, TEVA's acts of infringement have been committed willfully and with full and actual knowledge of ICN's patent rights and unless enjoined, will result in substantial unjust profits and unjust enrichment on the part of TEVA, in an as yet unascertained amount.

COUNT TWO

INTENTIONAL INTERFERENCE WITH PROSPECTIVE CONTRACTUAL RELATIONS

17. ICN re-alleges paragraphs 1-16 inclusive.

18. Upon information and belief, TEVA's acts of patent infringement upon FDA approval of TEVA's ANDA and TEVA's preparation for commercial development of the subject matter, claims or invention in the INTELLECTUAL PROPERTY have been and continue to be

improperly and intentionally interfering with ICN's prospective contractual relations with Schering Plough Corporation, and possibly others.

19. TEVA's acts of patent infringement, including inducing infringement, have resulted in, and are currently resulting in, substantial loss of prospective business revenue and good will in an amount as yet undetermined.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against TEVA as follows:

(a) For a preliminary and permanent injunction, pursuant to 35 U.S.C §§ 271(e)(4)(B) and 283, and Rule 65, Fed. R. Civ. P., enjoining TEVA and its subsidiaries, parent company, affiliate companies, officers, directors, agents, servants, employees and all persons acting for, with, by, through or under them, or any individual in active concert or in participation with them, and other related business entities, their successors and assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product or precursor that infringes the INTELLECTUAL PROPERTY.

(b) Requiring TEVA to prepare and deliver up to the Court a complete list of persons and entities for whom TEVA has made, used, sold, or offered to sell products which infringe Patents 5,767,097, 6,063,772, or 6,150,337, and to serve a copy of such list upon ICN's attorneys.

(c) Requiring TEVA to deliver to the Court any and all documents reflecting or relating to the manufacture, use, sale, or offer for sale of any product which infringes Patents 5,767,097; 6,063,772; or 6,150,337.

(d) Requiring TEVA to deliver up to the Court its inventory of all product which infringes Patents 5,767,097; 6,063,772; or 6,150,337.

(e) Requiring TEVA within 30 days after entry of judgment, to file with the Court and serve upon ICN's attorneys, a written report, under oath, setting forth in detail the manner in which TEVA has complied with paragraphs (a) through (d) above.

(f) Ordering TEVA to account for and pay over to ICN accumulated damages, including profits lost by ICN, sustained by reason of TEVA's unlawful acts of patent infringement herein alleged, and increasing the amount of recovery from TEVA as provided by law.

(g) Finding TEVA's infringement of ICN's INTELLECTUAL PROPERTY willful, and awarding increased damages, together with interest and costs, under 35 U.S.C. § 284.

(h) Finding the present case exceptional and awarding attorneys' fees to ICN under 35 U.S.C. §§ 271(e)(4) and 285.

(i) Ordering the FDA to not approve TEVA's ANDA No. 76-277.

(j) Providing ICN such other and further relief as the Court may deem appropriate.

Date. February 5, 2002

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ICN PHARMACEUTICALS, INC., ET AL., Plaintiffs, v. GENEVA PHARMACEUTICALS TECHNOLOGY CORP., ET AL., Defendants. AND RELATED CASES

CASE NO. CV 02-3544-MRP (FMOx) consolidated with (69-1), CV 02-3543-MRP (FMOx), CASE NO. CV 02-8142-MRP (FMOx)(70-1), CASE NO. CV 02-9358-MRP (FMOx)(54-1)(55-1)

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

2003 U.S. Dist. LEXIS 12024

July 14, 2003, Decided
July 14, 2003, Filed; July 15, 2003, Entered; July 15, 2003, Entered on ICMS

DISPOSITION: Defendants' motions for summary judgment granted. Patents found not infringed.

COUNSEL: [*1] For ICN PHARMACEUTICALS INC, plaintiff: Robert D Fish, David J Zoetewey, S Daniel Harbottle, Sandra P Thompson, Rutan & Tucker, Costa Mesa, CA. Edward V Filardi, Constance S Huttner, Douglas R Nemec, Todd J Tiberi, Skadden Arps Slate Meagher & Flom, New York, NY.

For GENEVA PHARMACEUTICALS, INC., defendant: John A Sturgeon, Matthew P Lewis, White & Case, Los Angeles, CA. Carol A Witschel, Dimitrios Drivas, Jeffrey J Oelke, Denise D Taliaferro, Chase J Romick, White & Case, New York, NY.

For GENEVA PHARMACEUTICALS TECHNOLOGY CORPORATION, counter-claimant: John A Sturgeon, Matthew P Lewis, White & Case, Los Angeles, CA. Carol A Witschel, Dimitrios Drivas, Jeffrey J Oelke, White & Case, New York, NY.

For ICN PHARMACEUTICALS INC, counter-defendant: Robert D Fish, David J Zoetewey, Sandra P Thompson, Rutan & Tucker, Costa Mesa, CA.

JUDGES: Honorable Mariana R. Pfaelzer, United States District Judge.

OPINIONBY: Mariana R. Pfaelzer

OPINION:

MEMORANDUM OF DECISION AND ORDER

Defendants Geneva Pharmaceuticals Technology Corp., et al. ("Geneva"), Teva Pharmaceuticals USA, Inc., et al. ("Teva"), and Three Rivers Pharmaceuticals, LLC ("Three Rivers") (collectively "Defendants") filed a joint [*2] Motion for Summary Judgment of Noninfringement requesting that this Court find that Defendants do not infringe the asserted claims of the patents at issue. Defendants concurrently filed a joint Motion for Summary Judgment of Invalidity requesting that this Court hold certain claims of the patents at issue invalid as anticipated by the prior art. The patents at issue are owned by Plaintiff ICN Pharmaceuticals, Inc., et al. ("ICN") and are as follows:

. *U.S. Patent No. 5,767,097* (issued June 16, 1998) ("the '097 patent")

. *U.S. Patent No. 6,063,772* (issued May 16, 2000) ("the '772 patent")

. *U.S. Patent No. 6,150,337* (issued Nov. 21, 2000) ("the '337 patent")

(collectively "the ICN patents"). The '772 patent is a continuation of the '097 patent, and the '337 patent is a continuation-in-part of the '772 patent. The ICN patents are generally directed to methods for administering ribavirin under a particular dosage, protocol, or concentration that promotes the response of a first type of cell, Th1, and suppresses the response of a second type of cell, Th2.

The motions came on for hearing on March 31, 2003. The Court heard oral argument and took the motions under [*3] submission. Having considered all of the submitted papers as well as the oral argument, the Court's decision is set forth below.

BACKGROUND

I. *The Hatch-Waxman Act*

In 1984, Congress adopted the *Drug Price Competition and Patent Term Restoration Act*, known generally as the Hatch-Waxman Act (the "Act"), to amend provisions of the patent statute and the *Food, Drug, and Cosmetic Act. Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1370-71 (Fed. Cir. 2002)*; *Allergan, Inc. v. Alcon Labs., Inc., Allergan, 324 F.3d 1322, 1325 (Fed. Cir. 2003)*. The Hatch-Waxman Act was adopted to strike a balance between two competing interests: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx, 276 F.3d at 1371*. The Act "provided brand name drug manufacturers with limited extensions of their patent terms in order to restore a portion of the market exclusivity lost through the lengthy process of drug development and [United States Food and Drug Administration ("FDA")] approval." *Allergan, 324 F.3d at 1325*. **[*4]** In addition, the Act "provided generic drug manufacturers with a patent infringement exemption for experimentation in connection with an application for FDA approval of a generic drug," *id.*, as well as "a shortened FDA approval process," id.

In order to market a drug for a particular use, a drug manufacturer must obtain FDA approval through the submission of a new drug application ("NDA") that includes the results of extensive testing, safety information, efficacy information, and composition data. *Id.* Once the NDA is approved, the drug manufacturer has "a five-year period of exclusive marketing for the approved drug, which can be extended by six months if the producer submits safety information relating to children." Id. The drug manufacturer is also required to submit patent information for any patent that "claims the drug for which the applicant submitted the application or which claims a method of using such drug." Id. (citing *21 U.S.C. § 355(b)(1)*). The FDA then lists the patent information in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known generally as the "Orange Book"). *Id. at 1325-26*. **[*5]**

Rather than submit its own set of extensive information, a potential generic drug manufacturer may file an abbreviated new drug application ("ANDA") for "the same drug that has been approved by the FDA" or for a drug that "is the bioequivalent of a drug that has been approved by the FDA." *Id. at 1326*. The ANDA allows the generic drug manufacturer to bypass the rigors of "proving the safety and efficacy of a drug that [is] already the object of an NDA." *Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1357 (Fed. Cir. 2003)*. In addition, the generic drug manufacturer is immune from patent infringement suits so long as the generic manufacturer's infringing acts are related to compliance with the FDA's regulation process. See *35 U.S.C. § 271(e)(1)* ("It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. . . ."). In the ANDA, the generic drug manufacturer must also certify, for every patent listed in the Orange **[*6]** Book with respect to the NDA-approved drug, either that the patent is a method of use patent that does not claim a use for which the applicant is seeking approval (known generally as a "little eight" statement) or provide certification "(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] application is submitted [known generally as "Paragraph IV certification"]." *21 U.S.C. § 355(j)(2)(A)(vii)-(viii)*.

If the generic drug manufacturer files a Paragraph IV certification, it must notify the owner of the patent. *Allergan, 324 F.3d at 1326*. "The patent owner then has 45 days to file an action for infringement in district court." *Id. at 1326-27*. "If the patent owner does not file suit within the required time period, the ANDA may be approved immediately, subject to applicable FDA regulations." *Id. at 1327*. "If the patent owner files an infringement action, the ANDA may not be approved until the date **[*7]** the court determines invalidity or non-infringement, the date the patent expires, or 30 months from the date the patent holder receives notice of the ANDA Paragraph IV certification (subject to judicial discretion), whichever occurs first." *Id.*

II. Ribavirin

Ribavirin was first synthesized in the early 1970s and patented by ICN in 1974. See *U.S. Patent No. 3,798,209* ("the '209 patent") (issued March 19, 1974) (expired March 19, 1991). In 1985, the FDA approved ribavirin aerosol as a monotherapy for treating infants with infections caused by respiratory syncytial virus. In the early 1990s, ICN experimented with methods for using ribavirin to treat patients with the chronic hepatitis C virus ("hepatitis C") and in 1994 attempted to obtain approval from the FDA for such use. The FDA denied approval on the ground that ICN's data failed to demonstrate ribavirin's efficacy.

Around that same time, Schering Corp. ("Schering") sold one of the leading drug treatments for hepatitis C, INTRON(R) A, a brand interferon alpha. In 1995, Schering and ICN entered into a license agreement that

allowed Schering to make and distribute an oral ribavirin product to be used for the [*8] treatment of hepatitis C. In exchange, ICN would receive royalties from Schering's future ribavirin sales. Schering filed a new drug application ("NDA") requesting approval to market ribavirin capsules in combination with interferon alpha injections for use in the treatment of hepatitis C, and in 1998, the FDA approved Schering's NDA. n1 In June 1998 and May 2000, the U.S. Patent and Trademark Office ("PTO") issued the '097 patent and the '772 patent, respectively. ICN then listed the '097 patent and the '772 patent in the Orange Book as covering a drug or method of using a drug that is part of Schering's approved ribavirin treatment. n2 Schering's non-patent NDA exclusivities for its ribavirin treatment have since expired.

n1 Schering sells its ribavirin capsules under the trade name REBETOL(R), its standard interferon alpha product under the trade name INTRON(R) A, and its pegylated interferon product under the trade name PEG-INTRON(R). Schering's ribavirin-interferon alpha combination products are marketed under the trade names REBETRON(R) and PEG-INTRON/Rebetol Combination Therapy.

n2 The '337 patent is not listed in the Orange Book.

[*9]

Defendants Geneva, Teva, and Three Rivers filed abbreviated new drug applications ("ANDAs") with the FDA pursuant to *section 505(j) of the Federal Food, Drug, and Cosmetic Act* seeking approval to market generic ribavirin capsules for use in combination with interferon alpha to treat hepatitis C. In addition, Defendants each filed a Paragraph IV certification, pursuant to *21 U.S.C. § 355(j) (2) (A) (vii) (IV)*, asserting that the '097 patent and the '772 patent will not be infringed by the manufacture, use, or sale of Defendant's ANDA products and that the patents are invalid and unenforceable.

ICN filed three separate patent infringement suits against Geneva, Teva, and Three Rivers on September 21, 2001, February 5, 2002, and May 24, 2002, respectively. All three suits were filed under *35 U.S.C. Section 271(e) (2) (A)* based on Defendants' filing of their ANDAs for generic ribavirin. ICN alleges that Defendants' manufacture and sale of generic ribavirin will induce physicians to infringe the ICN patents.

LEGAL STANDARDS

Summary judgment is appropriate when the moving party has demonstrated that there is no genuine issue as to [*10] any material fact and that the moving party is entitled to a judgment as a matter of law. *Fed. R. Civ. P. 56(c)*. A fact is material if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986)*. A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* Under the summary judgment standard, "the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id. at 255*. For a motion for summary judgment of noninfringement, the Court views the evidence in light of the preponderance of the evidence standard that would inhere at trial. See *Anderson, 477 U.S. at 252*; *Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1302 (Fed. Cir. 2001)* ("Literal infringement requires a patentee to prove by a preponderance of the evidence that every limitation of the asserted claim is literally met by the allegedly infringing device.").

NONINFRINGEMENT

Defendants contend that summary judgment [*11] of noninfringement should be granted because ICN is improperly alleging induced infringement of "off-label" use patents under *Section 271(e) (2)*. In addition, Defendants argue that summary judgment of no direct infringement should be granted because Defendants will not "use" the method claims asserted by ICN. Finally, Defendants contend that summary judgment of no induced infringement should be granted for either of two reasons (1) because physicians prescribing generic ribavirin in accordance with Defendants' proposed labeling instructions will not directly infringe, and (2) Defendants do not and will not have the intent to cause physicians to directly infringe the asserted claims of the ICN patents.

I. Claims Under *Section 271(e)(2)*

Defendants argue that ICN's claims of induced infringement under *Section 271(e)(2)* are improper because (A) the ICN patents are "off-label" use patents and (B) "a suit under *Section 271(e)* may not be based on inducing infringement." (J. Mem. of P. & A. in Supp. of Defs.' Mots. for Summ. J. of Noninfringement ("Noninfringement Motion") at 38.) Defendants offer several reasons as to why ICN's "suit under *Section 271(e)*" should not be allowed, [*12] namely that (1) "the Hatch-Waxman Act was only meant to apply to situations where an ANDA applicant is seeking approval to sell a pharmaceutical for its approved use;" (id. at 38) (2) "determination of [induced infringement claims] would require a court to speculate as to what promotional

efforts a generic defendant will undertake if its ANDA is approved;" (id. at 38-39) and (3) "allowing prospective inducement claims would give an over-broad construction to *Section 271(e)(2)*" and "would turn Congress' intent on its head." (id. at 39.).

Section 271(e)(2)(A) states the following:

> It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [i.e., an ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). This statute provides "an 'artificial' act of infringement that **[*13]** creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." n3 *Warner-Lambert, 316 F.3d at 1365*. Moreover, *Section 271(e)(2)(A)* supports claims of direct as well as induced infringement for a method of use patent (i.e., a patent that claims methods of using a drug rather than the drug itself). *Allergan, 324 F.3d at 1330-32*.

> n3 Without *Section 271(e)(2)*, the patentee would not have any act of infringement so long as the ANDA applicant's "infringing acts" were related to compliance with the FDA's regulation process. See *35 U.S.C. § 271(e)(1)*

Method of use infringement actions under *Section 271(e)(2)* are limited to those involving "controlling use patents," i.e., patents that claim an FDA-approved use of a drug. *Warner-Lambert, 316 F.3d at 1362*. In such cases, the patentee is precluded from suing the ANDA applicant under *Section* **[*14]** *271(e)(2). Allergan, 324 F.3d at 1334*.

A. Controlling Use Patents

Because *Section 271(e)(2)* infringement actions are limited to assertions of "controlling use" patents, summary judgment may be granted if the ICN patents are not "controlling use" patents (i.e., they claim a use other than that approved in ICN's NDA). See *Warner-Lambert, 316 F.3d at 1362*. Defendants contend that summary judgment of noninfringement should be granted because the ICN patents are not "controlling use" patents, but instead claim an "off-label" use of ribavirin. Defendants argue that the FDA-approved use of ribavirin is for administering ribavirin to treat hepatitis C in combination with interferon, whereas the ICN patents are directed to the "off-label" use of administering ribavirin to modulate Th1 and Th2 cell responses. n4 In contrast, ICN contends that the ICN patents are "controlling use" patents because they are directed to the treatment of hepatitis C, the same use approved under the NDA, and thus Defendants' ANDA filings fall within *Section 271(e)(2)*. (See Pls.' Consolidated Mem. of P. & A. in Opp'n to Defs.' Mots. for Summ. J. of Noninfringement and **[*15]** Invalidity ("Opp'n") at 27 (citing to '772 Patent, Claim 2).) n5

> n4 In support of their argument, Defendants claim that their ANDAs do not describe or recognize Th1/Th2 response modulation and that they instead state that the mechanism of action for ribavirin has not been established.

> n5 ICN also claims that the FDA has already "implicitly determined that [the ICN] patents are directed to the same use that is approved by the FDA." (Opp'n at 27-28 (relying on the FDA's rejection of Three Rivers' "little eight" claim that the ICN patents did not claim a use for which the applicant is seeking approval and requiring of Three Rivers to file a Paragraph IV Certification).) ICN's claim is misplaced. First, in support of its argument, ICN cites Exhibit 11 of the Decl. of Todd J. Tiberi in Supp. of Pls.' Opp'n to Defs.' Mots. for Summ. J. of Noninfringement and Invalidity ("Tiberi Decl.") which merely states that "[Three Rivers] may pursue an approval for this application under the *Federal Food, Drug, and Cosmetic Act, § 505(b)(2)* [if Three Rivers withdraws its amendment]." (Tiberi Decl. Ex. 11 at 1071.) In this statement, the FDA does not reject Three Rivers' little eight claim. In fact, *Section 505(b)(2)(B)* permits the filing of a "little eight" claim. Perhaps, ICN has other evidence of such "rejection," but such evidence has not be cited to this Court. Furthermore, "the FDA, pursuant to longstanding practice and its own regulations, and based on its acknowledged lack of expertise and resources, has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders' patent declarations and following their listing instructions." *American Bioscience, Inc. v. Thompson, 348 U.S. App. D.C. 77, 269 F.3d 1077, 1080 (D.C. Cir 2001)*. Thus, ICN would be hard pressed to argue that in this case, the FDA has reviewed the listed patents, made a

determination that such listing was proper, and decided that the patents are directed to the same use as approved by the FDA.

[*16]

The ICN patents are directed towards the use of ribavirin to treat a disease. Only two of the eight asserted claims, however, are specifically directed towards the treatment of hepatitis C. See '772 Patent, Claim 2 and Claim 9. The other asserted claims are arguably directed towards treatment of a broader set of diseases than that approved by the FDA but a set that would also encompass hepatitis C. Thus, the ICN patents may be "controlling use" patents because all of the asserted claims cover at least an FDA-approved use of ribavirin and possibly non-approved uses as well. In addition, as discussed *infra*, the "promotion of the Th1 response and suppression of the Th2 response" phrase merely recites an inherent effect of ribavirin when administered at certain dosages; the claimed use is treatment of a disease. Therefore, there is merit to ICN's argument that the claims are directed to the same use as approved by the FDA, i.e., treatment of hepatitis C, which clearly is a disease. That an inherent effect of the FDA-approved use is recited in the claims does not alter the conclusion that the claims cover the FDA-approved use.

For purposes of deciding whether or not summary judgment [*17] is proper, the court is to believe the evidence of the non-moving party and to draw all justifiable inferences in the non-moving party's favor. *Anderson, 477 U.S. at 255*. Thus, taking ICN's statements as true, ICN has raised a genuine issue of material fact regarding whether the ICN patents are "controlling use" patents. Thus, the Court rejects Defendants' contention that the patents at issue are "off-label" use patents as a basis of granting summary judgment of no induced infringement. Moreover, for the remainder of this Order, it is assumed that the ICN patents are not "off-label" use patents, but instead "controlling use" patents.

B. Induced Infringement Claims Proper

Section 271(e)(2) supports an action for induced infringement. *Allergan, 324 F.3d at 1331-32* ("While a *section 271(e)(2)* induced infringement claim may be speculative, it is not sufficiently so to contravene the case or controversy requirement."). Thus, Defendants' concerns about the "speculative" nature of such allegations, an "overbroad construction" of *Section 271(e)(2)*, and overturning Congressional intent have been rejected by the Federal Circuit.

Thus, the Court [*18] rejects Defendants' contention that an induced infringement suit under *Section 271(e)(2)* is improper as a basis of granting summary judgment of no induced infringement.

II. Claim Construction

The first step in an infringement analysis is that the claim is construed to determine the claim's proper scope and meaning. See *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1306 (Fed. Cir. 2000)*. The interpretation of patent claims is a matter of law reserved for the court. See *Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996)*. The court begins its claim construction by looking to the claims themselves. *Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 318 F.3d 1143, 1148 (Fed. Cir. 2003)*. In general, terms in a claim are given their plain, ordinary, and accustomed meaning to one of ordinary skill in the art at the time of invention. Id.; *Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081, 1088 (Fed. Cir. 2003)*. "After identifying the plain meaning of a disputed claim term, the court examines the written description and the drawings to determine [*19] whether the use of that term is consistent with the ordinary meaning of the term." *Prima Tek, 318 F.3d at 1148* (stating that such examination is "necessary to determine whether the patentee has disclaimed subject matter or has otherwise limited the scope of the claims"). "After examining the written description and the drawings, the same confirmatory measure must be taken with the prosecution history, since statements made during the prosecution of a patent may affect the scope of the invention." *Id. at 1149* (quoting *Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1343 (Fed. Cir. 2001))*. The court, however, may not use the prosecution history "to infer the intentional narrowing of a claim absent the applicant's clear disavowal of claim coverage." *Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1327 (Fed. Cir. 2003)*. Furthermore, while the specification and prosecution history may provide interpretive context for the claims, the court may not read limitations into the claims. *Rambus, 318 F.3d at 1088*.

The parties raise three primary claim construction issues. n6 First, the parties disagree [*20] as to the dosages of ribavirin ICN disclaimed during prosecution. Second, the parties dispute whether all of the asserted patent claims "require a cognitive focus on the immunomodulation of ribavirin." (Opp'n at 31.) Third, the parties dispute whether the preambles of the asserted claims are limitations to the claims.

n6 The parties did not raise any other claim construction issues. Accordingly, the non-disputed claim terms are given their common

meaning. Nothing in the specifications or the file histories dictates otherwise, nor did any party argue that the ordinary meaning should not apply.

A. The Dosage Terms

All of the asserted claims require, *inter alia*, administering ribavirin in an "amount" that promotes the Th1 response and suppresses the Th2 response. The asserted claims refer to this "amount" synonymously as "dosage," "dosage range," "protocol," and "concentration" (collectively referred to as "the dosage terms"). n7 The Court finds, and the parties agree, that the dosage terms should [*21] have their common meaning which includes "measured quantity," as in the claims, the dosage terms are used to convey the measured quantity of ribavirin to be administered to a patient.

n7 The parties treat all of the dosage terms the same for all three patents.

The parties agree that the ICN patents generally cover at least dosages below 800 mg/day and above 80 mg/day; hence the only dispute is whether specific dosage amounts are also within the scope of the claims. Defendants argue that ICN disclaimed dosages of 800 mg/day and reduced dosages of 600 mg/day if anemia is detected. (Noninfringement Motion at 14-19; see also Statement of Uncontroverted Facts and Conclus. of Law in Supp. of Defs.' Mots. for Summ. J. of Noninfringement at 15-16.) ICN argues that it did not disclaim such amounts, and therefore, such amounts should not be excluded. (Opp'n at 17-22.)

1. The '097 Patent

ICN asserts Claims 1 and 6 of the '097 patent (Pls.' Stmt. of Gen. Issues of Mat. Facts Re Noninfringement ("Pls. Stmt. [*22] of Facts - Noninfringement") at 11) which read as follows.

> 1. A method of modulating Th1 and Th2 response in activated T cells of a human patient comprising administering Ribavirin to the T cells in *a dosage* which promotes the Th1 response and suppresses the Th2 response.
>
> 6. A method of treating a patient having a disease which includes a viral component and a non-viral component, the non-viral component being characterized by reduced Th1 levels and increased Th2 levels in activated T-lymphocytes, comprising administering Ribavirin to the patient under *a protocol* sufficient to promote the Th1 response and suppress the Th2 response in a patient.

'097 Patent, Claims 1 and 6 (emphasis added). The asserted claims do not recite a specific amount, but instead require a "dosage" or "protocol" of ribavirin that "promotes the Th1 response and suppresses the Th2 response."

None of the references in the specification to "dosage" or "protocol" disclaim any specific amount or limit the scope of the claims. In addition, the references to the other dosage terms do not disclaim any specific amounts nor do they limit the scope of the claims.

Nevertheless, Defendants argue that [*23] ICN disclaimed dosages ranging from 800-1200 mg/day based upon the statement in the specification that "instead of administering ribavirin in its well-recognized role as an anti-viral agent, ribavirin is herein used in the treatment of imbalances in lymphokine expression." n8 '097 Patent at col. 4, lns. 14-17. While this statement makes it clear that ICN disclaimed "administering ribavirin in its well-recognized role as an anti-viral agent," what is unclear is what dosages, if any, ICN associated with this phrase when the application was filed. Defendants contend that when the patent application was filed, ICN knew that dosages ranging from 800-1200 mg/day were well-recognized uses of ribavirin as an anti-viral agent, and thus, ICN excluded such amounts from the claimed invention.

n8 During claim construction, the Court does not intimate any view as to whether the statements by the patentee were scientifically correct; the Court only looks to see what subject matter, if any, the patentee disclaimed.

Defendants' [*24] argument is misplaced. There is nothing in the intrinsic evidence that shows what ICN meant when it used the phrase "administering ribavirin in its well-recognized role as an anti-viral agent," nor is there anything in the record that shows that by using this phrase, ICN meant to limit the claim terms "dosage" and "protocol" to exclude dosages ranging from 800-1200 mg/day. The Court refuses to narrow the claims based on Defendants' assertions about what ICN allegedly intended to disclaim. Such a determination would be at best speculative and not based on ICN's clear disavowal of 800-1200 mg/day.

As for the prosecution history, in a response to a Final Office Action rejecting the claims as obvious over

prior art disclosing modulating lymphokine expression in T-cells, ICN distinguished its invention emphasizing that the inventor had discovered that ribavirin had "bimodal" effects, and that at the "normal effective dosage" of about 1000-1200 mg/day, ribavirin suppressed both Th1 and Th2, but at a "lower dose" of about 700-950 mg/day, ribavirin had the "surprising effect of suppressing [sic] Th1 and inducing [sic] Th2." (See Decl. of Todd J. Tiberi in Supp. of Pls.' Opp'n to Defs. [*25] ' Mots. for Summ. J. of Noninfringement and Invalidity ("Tiberi Decl.") Ex. 6 at 132 ('097 Patent File History, Paper No. 5 at 4).) ICN thus stressed that it was the lower dosage effect to which the patent claims were directed and clearly disclaimed dosages of 1000-1200 mg/day during prosecution of the '097 patent. n9

n9 Furthermore, during oral argument, ICN acknowledged that 1000-1200 mg/day was not part of the claimed dosage range. (R. at 29 ("We do concede that we disclaimed 1,000 to 1,200 and we always have.").)

2. The '772 Patent

ICN asserts Claims 1, 2, 5, and 9 of the '772 patent. (Pls. Stmt. of Facts - Noninfringement at 14-15.) Claims 2, 5, and 9 depend from, and thereby include the limitations of, Claim 1. The asserted claims are as follows.

> 1. A method of treating a disease responsive to ribavirin, comprising:
>
> recognizing progression of the disease as being mediated at least in part by Th1 lymphocytes;
>
> recognizing ribavirin as being effective to promote a Th1 response and suppress [*26] a Th2 response when administered in *a dosage range* below which both Th1 and Th2 responses are suppressed; and
>
> administering ribavirin to a patient having the disease within the dosage range.
>
> 2. The method of claim 1 wherein the disease comprises Hepatitis C.
>
> 5. The method of claim 1 wherein the disease comprises Hepatitis C and *the dosage range* achieves a blood serum level in the patient averaging approximately 0.25-6.7 [mu] g/ml [sic, [mu] M] of ribavirin.
>
> 9. The method of any of claims 1-7 further comprising administering interferon alpha to the patient.

'772 Patent, Claims 1, 2, 5, and 9 (emphasis added). Of the asserted claims, only Claim 5 and Claim 9, as it applies to Claim 5, include a specific dosage range of 0.25-6.7 [mu] M (i.e., 30-800 mg/day). n10 Because these claims specifically include dosages of 600 mg/day and 800 mg/day, it is clear that in these claims, ICN did not disclaim amounts of 800 mg/day and 600 mg/day. The other claims do not recite a specific amount, but instead require a "dosage range" of ribavirin "below which both Th1 and Th2 responses are suppressed" and that is "effective to promote a Th1 response and suppress a Th2 response. [*27] "

n10 ICN states that the units [mu] g/ml should have been [mu] M. (Opp'n at 20, n.43.) This correction is supported by the '772 patent specification, which refers to ribavirin in units of [mu] M and also by the discussion of similar statements in the '337 patent regarding ribavirin's effects. See e.g., '337 Patent at col. 4, lns. 34-39.

The '772 patent specification is the same as the '097 patent specification. Accordingly, none of the references in the specification to "dosage range" or to any other dosage term disclaim any specific amounts or limit the scope of the claims.

As for the prosecution history, because the '772 patent is a continuation of the '097 patent, the prosecution history of the '097 patent applies with equal force to the interpretation of the '772 patent claims. See *Biovail, 239 F.3d at 1301* (citing *Elkay Mfg. Co. v. EBCO Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999)* ("When multiple patents derive from the same initial application, the prosecution [*28] history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.")). As noted above, ICN clearly disclaimed dosages of 1000-1200 mg/day during prosecution of the '097 patent. During prosecution of the '772 patent, in a preliminary amendment dated October 13, 1998, ICN stated that "the highest level presently contemplated for achieving the inverse Type 1/Type 2 relationship is therefore about 11.4 mg/kg/day, or about 800 mg for a typical 70 kg patient." (Tiberi Decl. Ex. 8 at

445 ('772 Patent File History, Paper No. 7 at 3).) This statement evidences that ICN disclaimed dosage amounts above 800 mg/day. n11 In addition, ICN also submitted an information disclosure statement ("IDS") distinguishing several references based, at least in part, on their dosage amounts thereby disclaiming dosage amounts of 80 mg/day and below and also dosages of various amounts that were given as "ramp-up" dosages and "subtreatment dosages," i.e., temporary measures to counteract side effects. n12 (Tiberi Decl. Ex. 8 at 411-28 ('772 Patent File History, Paper No. 4).)

n11 Because ICN used the language "about 800 mg" rather than "800 mg," ICN may have an argument that it did not disclaim amounts near 800 mg. Such arguments, however, have no bearing on this Order. [*29]

n12 More specifically, ICN distinguished references with dosages ranging from 1000 to 1200 mg/day as having a dosage "significantly greater than the presently claimed [dosage]" (Tiberi Decl. Ex. 8 at 414-25) and distinguished dosages ranging from 600 to 1200 mg/day on the premise that the dosages that fell within the ranges of the claimed dosage were disclosed as "merely a ramp-up dosage rather than a 'treatment' dosage" (id.). A dosage of 200 mg/day was distinguished on the basis that it was used as a "'subtreatment dose," i.e., a temporary measure to counteract side effects. (Id.) Also, a dosage of 80 mg/day was distinguished from the claimed dosage as being "significantly less than that presently claimed." (Id.) All of these references were also distinguished because they did not teach or suggest that the authors "recognized ribavirin as being effective to promote a Th1 response and suppress a Th2 response." (Id.)

The Court declines to adopt Defendants' position that ICN also disclaimed the amount of 800 mg/day. ICN distinguished references with dosages of 800 mg/day *solely* [*30] on the basis that such references did not teach or suggest that the authors "recognized ribavirin as being effective to promote a Th1 response and suppress a Th2 response." (Tiberi Decl. Ex. 8 at 414-25.) One reference disclosed a dosage of 800-1200 mg/day wherein ICN distinguished it from the claimed dosage as being "significantly greater than that presently claimed." (Tiberi Decl. Ex. 8 at 418.) ICN argues that this was at most a stray remark and that this statement was meant to apply only to some portion of the dosage range above 800 mg/day. All other references to 800 mg/day were distinguished as either a ramp-up dosage or they were not distinguished using the dosage amount. Furthermore, during prosecution, ICN specifically stated that the dosage that achieved the inverse relationship included 800 mg/day and attempted to include tables that indicated that dosages of 800 mg/day were within the claimed dosage range. ICN did not clearly disclaim the dosage amount of 800 mg/day.

Thus, the term "dosage range" as used in the '772 patent claims is construed as "a treatment dosage not including greater than 800 mg/day and not including 80 mg/day and less" wherein "treatment dosage" excludes [*31] ramp-up dosages and subtreatment dosages to counteract side effects. Furthermore, because the '772 patent is a continuation of the '097 patent, the same construction applies to the terms "dosage" and "protocol" in the '097 patent. n13

n13 Because both patents have the same priority date and the same specification, statements made during prosecution of the '772 patent relating to references that are also prior art to the '097 patent should apply with equal force to the '097 patent.

3. The '337 Patent

ICN asserts Claims 1 and 5 of the '337 patent. (Pls. Stmt. of Facts - Noninfringement at 17.) The asserted claims are as follows.

> 1. A method of inversely modulating Type 1 and Type 2 responses of lymphocytes contained within an environment by adding ribavirin to the lymphocytes in *a concentration* which increases the Type 1 response and suppresses the Type 2 response.
>
> 5. A method of inhibiting a virus by growing a virus in an environment having lymphocytes which produce Type 1 and Type 2 cytokine [*32] responses, and adding ribavirin to the environment in *a concentration* which increases the Type 1 response and suppresses the Type 2 response.

'337 Patent, Claims 1 and 5 (emphasis added). The asserted claims do not recite a specific amount, but instead require a "concentration" of ribavirin that "increases the Type 1 response and suppresses the Type 2 response."

Furthermore, none of the references in the specification to "concentration" disclaim any specific amount or limit the scope of the claims. In addition, the references to the other dosage terms do not disclaim any specific amounts nor do they limit the scope of the claims.

Because the '337 patent is a continuation-in-part of the '772 patent, which is a continuation of the '097 patent, the prosecution histories of the '097 patent and the '772 patent apply with equal force to the interpretation of the '337 patent claims. See *Biovail, 239 F.3d at 1301*. In the prosecution of the parent applications, ICN clearly disclaimed dosages above 800 mg/day and below 80 mg/day and made it clear that the term "dosage range" meant "treatment dosage" rather than a "ramp-up dosage" or a "subtreatment dosage to counteract **[*33]** side effects." n14 There is nothing in the file history of the '337 patent showing that ICN clearly disclaimed any additional amounts.

n14 In addition, the '337 patent specification notes in Table 2 that 1000-1500 mg/day are "previously known dosage ranges" of ribavirin thereby providing support that ICN disclaimed dosages above 1000 mg/day. Further, ICN submitted the same IDS with the same limiting statements as it did during the prosecution of the '772 patent.

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Thus, the term "concentration" as used in the '337 patent claims is construed as "treatment dosage not including greater than 800 mg/day and not including 80 mg/day and less" wherein "treatment dosage" excludes ramp-up dosages or subtreatment dosages to counteract side effects.

B. "Cognitive Focus"

ICN also argues that all of the asserted claims require "a cognitive focus on the immunomodulation of ribavirin" (Opp'n at 31) and that "ribavirin is given for the purpose of modulating the Th1/Th2 balance" (Opp'n at 5). ICN uses the term "cognitive **[*34]** focus" to refer to a "subjective recognition" (i.e., human realization) that it argues is required by the claims. (Opp'n at 33.) ICN notes, however, that "the '097 and '337 patent claims do not explicitly require the person administering ribavirin to recognize the immunomodulatory effect of the drug[;] however, they require that ribavirin be administered for the purpose of 'enhancing the Th1 response and suppressing the Th2 response' during the treatment of hepatitis C." (Opp'n at 32 n.64.)

Contrary to ICN's contentions, the asserted claims of the '097 patent and the '337 patent do not include an element of "cognitive recognition." Claim 1 of the '097 patent merely requires that ribavirin is administered in a dosage which promotes the Th2 response and suppresses the Th2 response, and Claim 6 requires that ribavirin is administered under a protocol sufficient to promote the Th1 response and suppress the Th2 response. Claims 1 and 5 of the '337 patent require only that ribavirin is added in a concentration which increases the Type 1 response and suppresses the Type2 response. Nothing in the claim language requires the administrators to "recognize" that such responses are occurring **[*35]** or that they specifically administer ribavirin "for the purpose of modulating the Th1/Th2 balance." Moreover, there is nothing in the specifications or file histories that provides any rationale under which "cognitive recognition" should be read into the claims, nor does ICN point to any basis under which the Court could read such limitation into the claims. n15 See *Rambus, 318 F.3d at 1088*. None of the asserted claims of the '097 patent or the '337 patent require any "cognitive recognition."

n15 As support for its assertion that the claims of the '097 patent and the '337 patent include a volitional component, ICN merely cites to the claims of the patents (see e.g., Opp'n at 5 n.5; id. at 32 n.64), or fails to provide any citation (see e.g., id. at 5, ln. 9; id. at 31, ln. 23; id. at 33, ln. 4; id. at 34, ln. 14).

Claim 1 of the '772 patent expressly includes the limitations of "recognizing progression of the disease" and "recognizing ribavirin as being effective to promote **[*36]** a Th1 response and suppress a Th2 response" '772 patent, Claim 1. Furthermore, all of the other asserted '772 patent claims depend from and include the elements of Claim 1. '772 patent, Claim 2, 5, and 9. Thus, the asserted claims of the '772 patent include elements of cognitive recognition.

C. The Preambles

In general, a preamble to a claim is not treated as a limitation if, for example, it merely sets forth the purpose or intended use of the invention. *Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999)*. Furthermore, "an intended use or purpose usually will not limit the scope of the claim because such statements usually do no more then define a context in which the invention operates." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1345 (Fed. Cir. 2003)*. Thus, "if the body of the claim sets out the complete invention, and the preamble

is not necessary to give life, meaning and vitality to the claim, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." *Schumer v. Laboratory Computer Sys., Inc., 308 F.3d 1304, 1310 (Fed. Cir. 2002)* [*37] (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1373-74 (Fed. Cir. 2001))*. The preamble may be considered a limitation, however, if the "preamble provides antecedents for ensuing claim terms and limits the claim accordingly." *Boehringer, 320 F.3d at 1345*.

a. The Asserted Claims of the '097 Patent

The preamble for Claim 1 is "[a] method of modulating Th1 and Th2 response in activated T cells of a human patient." '097 Patent, Claim 1. The preamble sets forth a result of the invention in that it states an effect that occurs when the claimed method is practiced. n16 Furthermore, even though the preamble provides the antecedent bases for the "T cell," "Th1 response," and "Th2 response" limitations, the body of the claim sets out the complete invention and the antecedent bases do not limit the claim any more than the terms do within the body of the claim. Thus, the preamble is not a limitation.

n16 The Court has already determined that the preamble, or any other part of the claim, does not require cognitive recognition by the administering party. Thus, the preamble does not require that the ribavirin is administered "for its function in modulating Th1 relative to Th2."

[*38]

The preamble for Claim 6 is "[a] method of treating a patient having a disease which includes a viral component and a non-viral component, the non-viral component being characterized by reduced Th1 levels and increased Th2 levels in activated T-lymphocytes." '097 Patent, Claim 6. The preamble merely sets forth a use of the invention. Furthermore, even though the preamble provides the antecedent bases for the "patient," "Th1 response," and "Th2 response" limitations, the body of the claim sets out the complete invention and such antecedent bases do not limit the claim any more than the terms do within the body of the claim. Thus, the preamble is not a limitation.

b. The Asserted Claims of the '722 Patent

The preamble for Claim 1 is "[a] method of treating a disease responsive to ribavirin." '772 Patent, Claim 1. The preamble merely sets forth a use of the invention and is therefore not a limitation. All of the other asserted claims of the '772 patent depend from Claim 1 and therefore include the same preamble as Claim 1. Thus, the preambles for Claims 2, 5, and 9 are not limitations.

c. The Asserted Claims of the '337 Patent

The preamble for Claim 1 is "[a] [*39] method of inversely modulating Type 1 and Type 2 responses of lymphocytes contained within an environment." '337 Patent, Claim 1. The preamble merely sets forth a result of the invention in that it states an effect that occurs when the claimed method is practiced. Furthermore, even though the preamble provides the antecedent bases for the "lymphocytes," "Type 1 response," and "Type 2 response" limitations, the body of the claim sets out the complete invention and such antecedent bases do not limit the claim any more than the terms do within the body of the claim. Thus, the preamble is not a limitation.

The preamble for Claim 5 is "[a] method of inhibiting a virus." '337 Patent, Claim 5. The preamble merely sets forth a result of the invention in that it states an effect which occurs when the claimed method is practiced, and therefore is not a limitation.

Thus, none of the preambles of the asserted claims are limitations.

III. Direct Infringement by Defendants

An infringement analysis under *Section 271(e)(2)* is conducted under a traditional direct infringement analysis. See *Warner-Lambert, 316 F.3d at 1365* ("Once jurisdiction is established, . . [*40] . the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, . . . the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed."). A traditional direct infringement analysis is governed by *35 U.S.C. Section 271(a)* which states that "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent." *35 U.S.C. § 271(a)*. Under *Section 271(e)(2)*, the analysis turns on "whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Warner-Lambert, 316 F.3d at 1364*. Thus, the proper inquiry is "whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent." See *id. at 1366* (citing *Bristol-Myers Squibb Co. v. Royce Lab. 69 F.3d 1130, 1135 (Fed. Cir. 1995))*. The party seeking relief under *Section 271(e)(2)* "must prove by a preponderance [*41] of the evidence that what is to be sold will infringe." *Warner-Lambert, 316 F.3d at 1366*.

All of the asserted claims are method claims directed to "methods of treating," "methods of modulating," and

"methods of inhibiting." '097 Patent; '772 Patent; '337 Patent. Accordingly, a party directly infringes under *Section 271(a)* if the party "uses" any of the claimed methods. See *Schumer, 308 F.3d at 1309 n.3* ("A method claim is infringed only by one practicing the patented method.").

Defendants themselves will not directly infringe because even if they manufactured and marketed generic ribavirin, they would not be "treating," "modulating," or "inhibiting." Such use would be performed, if at all, by the physicians.

> Pharmaceutical companies do not generally treat diseases; rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians. Pharmaceutical companies also occasionally give samples of drugs to doctors and hospitals. In none of these cases, however, does the company itself *treat* the disease.

Warner-Lambert, 316 F.3d at 1363 n.7. While there [*42] may be exceptions to the general rule, ICN has not alleged that any of the exceptions apply in this case (e.g., that any of the Defendants would "use" the claimed methods). Further, ICN does not dispute that "Defendants do not employ doctors who prescribe ribavirin." (Pls.' Stmt. of Facts - Noninfringement at 40.) Thus, there are no genuine issues of material fact with respect to whether Defendants directly infringe the method claims. Summary judgment of no direct infringement is GRANTED in favor of all three Defendants for the asserted claims of the ICN patents.

IV. Induced Infringement by Defendants

An induced infringement claim under *Section 271(e)(2)* is conducted under a traditional induced infringement analysis. *Warner-Lambert, 316 F.3d at 1365.* A traditional induced infringement analysis is governed by *35 U.S.C. Section 271(b)* which states that "whoever actively induces infringement of a patent shall be liable as an infringer." *35 U.S.C. § 271(b).* "In order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement and second that the alleged infringer [*43] knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minnesota Mining & Mfg. Co. v. Chemgue, Inc., 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)* (citations omitted). n17

> n17 While the direct infringement analysis is the same as in the section above, it is noted that the previous section reviewed whether Defendants' themselves would directly infringe. This section reviews whether there are other parties (e.g., physicians) that Defendants would induce or encourage to directly infringe the patents.

A. Direct Infringement by Physicians

For a method claim, the direct infringement analysis is a two-step procedure: (1) the claim is construed by the court to determine the proper claim scope and meaning (as set forth above); and (2) the properly construed claim is compared to the accused method to determine whether the accused method meets all of the limitations of the claim. See *Elekta, 214 F.3d at 1306.* To infringe, the accused method [*44] must meet every limitation of the asserted claims, either literally or by equivalents. *Id.*

1. Claim Construction

As discussed above, the terms "dosage," "dosage range," "protocol," and "concentration" as used in the claims of the ICN patents are construed as "treatment dosage not including greater than 800 mg/day and not including 80 mg/day and less" wherein "treatment dosage" excludes ramp-up dosages and subtreatment dosages to counteract side effects. In addition, the asserted claims of the '097 patent and the '337 patent do not include limitations of "cognitive recognition." Furthermore, the preambles are not limitations.

2. Comparison of Direct Infringers' Actions with Construed Claims

Each of the Defendants filed an ANDA with the FDA seeking approval to market a generic form of 200-milligram ("mg") ribavirin capsules for use in combination with interferon to treat hepatitis C. The ANDAs include labeling recommending that the ribavirin capsules are administered at a treatment dosage of 1000 mg/day for patients weighing 75 kilograms ("kg") or less and 1200 mg/day for patients weighing more than 75 kg. (Noninfringement Motion at 7 (citing Decl. of Chase [*45] Romick in Supp. of Defs.' Mots. for Summ. J. re: Invalidity and Noninfringement ("Romick Decl.") Ex. 26; Decl. of Karen J. Jacobs in Supp. of Mots. for Summ. J. of Noninfringement and Invalidity ("Jacobs Decl.") Exs. 2 and 3; and Decl. of Stephanie L. Nagel in Supp. of Three Rivers Pharms.' Mot. for Summ. J. of Noninfringement ("Nagel Decl.") Ex. 2).) In addition, Defendants' labeling includes a reduced subtreatment dosage of 600 mg/day of ribavirin when a patient's hemoglobin level falls below a certain level. (Mem. of P. & A. in Supp. of Defs.' Mot. for

Summ. J. of Invalidity ("Invalidity Motion") at 6 (citing Romick Decl. Ex. 26; Jacobs Decl. Ex. 2.; Decl. of Steven Maddox ("Maddox Decl.") Ex. 5).) This labeling is essentially the same as the labeling for Schering's originally approved ribavirin capsules. (See Opp'n at 10.)

In August 2001, Schering modified its labeling to add an 800 mg/day treatment dosage of ribavirin in combination with pegylated interferon. Defendant Three Rivers revised its proposed labeling to include the 800 mg/day treatment dosage instruction, but has since withdrawn the modification; n18 Defendants Geneva and Teva have not requested a modification [*46] to add such a dosage. ICN argues that even though Geneva and Teva have not yet modified their labeling, the FDA will require them to do so in order to have their ANDAs approved. ICN's primary argument is based on the FDA's original refusal to allow Three Rivers to withdraw its reference to the 800 mg/day dosage. (See Opp'n at 13-14.) The FDA has since stated that it will allow Three Rivers to withdraw its modification.

n18 On January 8, 2003, Three Rivers attempted to withdraw the revision so that it could delete all references to the 800 mg/day dosage. (Nagel Decl. Ex. 2.) On February 5, 2003, the FDA rejected Three Rivers' attempted withdrawal stating that "since your drug product is limited to the use in combination with Intron-A(R) only, the application cannot be approved as an ANDA because the labeling would be different from the labeling of the referenced listed drug, Rebetol(R) by Schering Corporation." (Tiberi Decl. Ex. 11 at 1071.) In response, Three Rivers formally withdrew its January 8, 2003 Amendment thereby leaving in all references to the 800 mg/day dosage. (See id. Ex. 12 at 1073.) On June 27, 2003, the FDA stated that "generic drug applicants can 'carve-out' the information in their labeling for use of ribavirin with pegylated interferon." (Notice of Recent FDA Ruling Ex. 1 at 1.) On July 8, 2003, Three Rivers stated that it is "in the process of amending its proposed labeling to remove references to 800 mg/day and will only include 1000 mg/day and 1200 mg/day." (Three Rivers' Joinder in the Am. Reply Mom. of P. & A. in Supp. of Geneva's and Teva's Mots. for Summ. J. of Noninfringement at 3.)

[*47]

Nonetheless, an infringement case is "limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." Warner-Lambert, 316 at 1364. "The ANDA must be judged on its face for what an accused infringer seeks the FDA's approval to do. *Section 271(e)(2)* does not encompass 'speculative' claims of infringement." Id. (rejecting the patentee's request to base the ruling on the intent and knowledge of the accused induced infringer as of the date of hypothetical FDA approval). Thus, regardless of what the future labeling of Geneva, Teva, and Three Rivers might be, this *Section 271(e)(2)* suit focuses only on their current proposed labeling instructions. Accordingly, this Order is based upon the fact that the current proposed labeling instructions of Geneva, Teva, and Three Rivers include 1000-1200 mg/day treatment dosages of ribavirin with standard interferon as well as reduced subtreatment dosages of 600 mg/day of ribavirin when a patient's hemoglobin levels fall below a certain level. None of the Defendants' labeling includes an 800 mg/day treatment dosage of ribavirin in combination with pegylated [*48] interferon.

Thus, physicians prescribing ribavirin in accordance with the instructions of Defendants would not literally infringe the asserted claims of the ICN patents because the recommended treatment dosages fall outside of the claimed dosage amounts. Physicians using reduced subtreatment dosages of 600 mg/day would not literally infringe because dosages for such purposes were disclaimed during prosecution.

ICN also argues, however, that many physicians will administer Defendants' ribavirin, based on their patients' weight, at treatment dosages of about 800 mg/day and that such administration will constitute literal infringement. Assuming the evidence of ICN is true and drawing all justifiable inferences in favor of ICN for purposes of this Order, *Anderson, 477 U.S. at 255*, such physicians may be found to directly infringe the asserted claims of the patents (i.e., by treating the patients with a claimed dosage of generic ribavirin). Thus, the Court rejects Defendants' contention that there is no genuine issue of material fact that the physicians will not directly infringe as a basis of granting summary judgment of no induced infringement. Moreover, it is hereafter [*49] assumed, for purposes of this Order, that ICN will be able to show that there is direct infringement by physicians prescribing Defendants' generic ribavirin.

B. Induced Infringement by Defendants

In addition to showing an act of direct infringement, the plaintiff must also show that the alleged induced infringer had the specific intent to cause the direct infringement. See *Minnesota Mining & Mfg., 303 F.3d at 1304-05*. That the alleged induced infringer knew of the acts alleged to constitute direct infringement is not enough, the plaintiff must have "proof of actual intent to cause the acts which constitute the infringement."

Warner-Lambert, 316 F.3d at 1363 (citing *Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990)*; see also *Warner-Lambert, 316 F.3d at 1365* ("Especially where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent."). The patentee must show that "the accused infringer knowingly aided and abetted another's direct infringement [*50] of the patent." *Id. at 1363* (citations omitted). Proof of intent does not require direct evidence, but may be shown using circumstantial evidence. *Id.* In order to raise a genuine issue of material fact, the plaintiff must provide evidence that the induced infringer "has or will promote or encourage doctors to infringe the . . . patent." *Id. at 1364.*

1. The '097 Patent

The asserted claims of the '097 patent essentially cover the administration of ribavirin in a treatment dosage which promotes the Th1 response and suppresses the Th2 response. There is no cognitive element required by the claims. In addition, treatment dosages that cause the claimed effect do not include 1000-1200 mg/day.

Defendants' current proposed labeling instructions include 1000-1200 mg/day treatment dosages of ribavirin with standard interferon as well as a reduced subtreatment dosages of 600 mg/day of ribavirin when a patient's hemoglobin level falls below a certain level. Thus, their labeling instructions do not show any specific intent of inducement as the instructions do not encourage physicians to administer ribavirin at a treatment dosage which promotes the [*51] Th1 response and suppresses the Th2 response. Defendants' knowledge that, despite their labeling instructions, physicians may on their own administer a treatment dosage of ribavirin within the claimed range (e.g., based on the patient's weight) is not sufficient to constitute the specific intent required for induced infringement. Rather, ICN must provide evidence that the alleged induced infringer has or will promote or encourage physicians to infringe the patent. See *Warner-Lambert, 316 F.3d at 1364.* ICN has not done so. Thus, summary judgment of no induced infringement of the asserted claims of the '097 patent is GRANTED based on lack of specific intent.

2. The '772 Patent

The asserted claims of the '772 patent essentially cover methods of treating a disease responsive to ribavirin by administering ribavirin at a treatment dosage which promotes the Th1 response and suppresses the Th2 response. In addition, the claims require that the direct infringer "recognize progression of the disease as being mediated at least in part by Th1 lymphocytes" and "recognize ribavirin as being effective to promote a Th1 response as suppress a Th2 response" In addition, [*52] the claimed dosage does not include 1000-1200 mg/day, but includes 800 mg/day.

As discussed above, Defendants' proposed labeling is directed to ribavirin capsules for use in combination with interferon to treat hepatitis C. None of Defendants' proposed labeling instructions "promote or encourage doctors" to "recognize progression of the disease as being mediated at least in part by Th1 lymphocytes," or to "recognize ribavirin as being effective to promote a Th1 response and suppress a Th2 response when administered in a dosage range below which both Th1 and Th2 responses are suppressed;" the instructions do not even make any reference to Th1 or Th2.

To overcome a motion for summary judgment, ICN must raise a genuine issue of material fact that the alleged induced infringer has or will promote or encourage physicians make the claimed recognitions. See *Warner-Lambert, 316 F.3d at 1364.* ICN has failed to raise any such issues. Accordingly, summary judgment of no induced infringement of the asserted claims of the '772 patent is GRANTED based on lack of specific intent.

3. The '337 Patent

The asserted claims of the '337 patent essentially cover adding ribavirin [*53] to the environment in a treatment dosage which increases the Type 1 response and suppresses the Type 2 response. There is no cognitive element required by the claims. In addition, treatment dosages that cause the claimed effect do not include 1000-1200 mg/day, but include 800 mg/day.

Defendants' current proposed labeling instructions include 1000-1200 mg/day treatment dosages of ribavirin with standard interferon as well as reduced subtreatment dosages of 600 mg/day of ribavirin when a patient's hemoglobin level falls below a certain level. Thus, Defendants' labeling instructions do not show any specific intent of inducement as the instructions do not encourage physicians to add ribavirin in a concentration which increases the Th1 response and suppresses the Th2 response. Defendants' knowledge that, despite the labeling instructions, physicians may on their own administer a treatment dosage of ribavirin within the claimed concentration (e.g., based on the patient's weight), is not sufficient to constitute specific intent required for induced infringement. Rather, ICN must provide evidence that the alleged induced infringer has or will promote or encourage physicians to infringe the [*54] patent. See *Warner-Lambert, 316 F.3d at 1364.* ICN has not done so. Thus, summary judgment of no induced infringement of the asserted claims of the '337 patent is GRANTED based on lack of specific intent.

V. CONCLUSION

Summary judgment of no direct infringement by Defendants Geneva, Teva, and Three Rivers as to the asserted claims of the '097 patent, the '772 patent, and the '332 patent is GRANTED.

Summary judgment of no induced infringement by Defendants Geneva, Teva, and Three Rivers as to the asserted claims of the '097 patent, the '772 patent, and the '332 patent is GRANTED.

INVALIDITY

Defendants also contend that they are entitled to summary judgment of invalidity under *35 U.S.C. Section 102(b)* arguing that ICN's claimed use of ribavirin is anticipated by the anti-viral use of ribavirin published in the prior art. (Invalidity Motion at 1.) The Court found above that Defendants do not infringe the asserted claims of the ICN patents, and thus, the Court declines to rule on invalidity.

Nonetheless, while the Court recognizes that patent claims have a presumption of validity, *35 U.S.C. § 282*, **[*55]** the Court has strong reservations about the validity of the ICN patents, especially in light of the 1994 Brillanti article ("Brillanti"). n19

> n19 Published in September 1994, the Brillanti authors disclose a study conducted with twenty adults to "evaluate whether ribavirin and IFN- [proportional] [i.e., interferon alpha] in combination could be effective in IFN- [proportional] -resistant chronic hepatitis C." (Maddox Decl. Ex. 14 (Stefano Brillanti et al. ("Brillanti"), A Pilot Study of Combination Therapy with Ribavirin Plus Interferon Alpha for Interferon Alpha-Resistant Chronic Hepatitis C, 107 Gastrointerology 812 (1994)).) "The 20 patients were randomly assigned to receive a 6-month course of either ribavirin combined with IFN- [proportional] (10 patients) or IFN- [proportional] alone (10 patients) . . . . The 10 patients assigned to receive combination therapy were given 800 mg/day ribavirin . . . orally in two daily doses." Id. Brillanti is clearly prior art to all of the ICN patents in that it was published more than one year before the earliest filing date of the patents, January 23, 1996.

[*56]

Brillanti discloses administering ribavirin in treatment dosages of 800 mg/day, a dosage within the range claimed by the ICN patents. ICN attempts to argue that Brillanti does not anticipate because: (1) Brillanti does not disclose the "promotion of the Th1 response and the suppression of the Th2 response," and (2) Brillanti does not disclose the "recognition" of such promotion and suppression.

I. Inherency

That Brillanti does not specifically disclose the "promotion of the Th1 response and the suppression of the Th2 response," does not necessarily save the claims from anticipation if that property was inherent in the prior art. The discovery of "a previously unappreciated property of a prior art composition," "a scientific explanation for the prior art's functioning," or "newly discovered results of known processes directed to the same purpose" does not render the old composition new to the discoverer and such discoveries are not patentable because they are inherent in the prior art. See *Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999)*; *Bristol-Myers, 246 F.3d at 1376*; see also *Brassica Protection Products LLC, 301 F.3d 1343, 1350-51 (Fed. Cir. 2002)* **[*57]** (finding that mere recognition of something interesting about the prior art does not constitute invention).

ICN argues that even if the property was inherent, Brillanti cannot anticipate unless there is proof that the property was recognized by persons of ordinary skill in the art. (Opp'n at 31 (citing *Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002)* (stating that under inherency, a reference will anticipate "if the missing element 'is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill") (quoting *Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991)))*.)

Other cases find, however, that prior art may anticipate even if those of ordinary skill in the art did not recognize the inherent characteristic or functioning of the prior art. *Atlas Powder, 190 F.3d at 1349* ("Insufficient prior understanding of the inherency properties of a known composition does not defeat a finding of anticipation."); *id. at 1347* ("If the prior art necessarily functions in accordance with, or includes, the claimed limitations, **[*58]** it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.") (citations omitted). The Court notes that Rosco/Continental Can and Atlas take different views on whether the inherent property must be recognized by those of ordinary skill; however, the tension between the two positions seems to disappear when one realizes that the positions are applied to differing circumstances.

> [The Continental Can] requirement, that a person of ordinary skill in the art must recognize that the missing descriptive matter is necessarily present in the reference, may be sensible for claims that recite limitations of structure, compositions of matter, and method steps which could be inherently found in the prior art. Such recognition by one of ordinary skill may be important for establishing that the descriptive matter would inherently exist for every combination of a claim's limitation. Theoretical mechanisms or rules of natural law that are recited in a claim, that themselves are not patentable, however, do not need to **[*59]** be recognized by one of ordinary skill in the art for a finding of inherency. A person of ordinary skill does not need to recognize that a method or structure behaves according to a law of nature in order to fully and effectively practice the method or structure."

EMI Group North America, Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350-51 (Fed. Cir. 2001). Moreover, the inherent effect at issue in the ICN patent claims appears to relate to a law of nature - something that would have necessarily existed in the prior administration of ribavirin of 800 mg/day.

II. Recognition

The Court also questions ICN's attempt to claim the "recognition" of an inherent property, which according to ICN is a "cognitive focus" element that can only be performed by a human. (Opp'n at 31-32.) The Federal Circuit has already stated that one who discovers a "previously unappreciated property of a prior art composition" or a "scientific explanation for the prior art's functioning" has not invented something new as such properties were inherent within the prior art composition. See *Atlas Powder, 190 F.3d at 1347 (Fed. Cir. 1999)*. Accordingly, **[*60]** one who makes such a discovery may not obtain a patent claiming the discovery. See *id. at 1347-48* (discussing *Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985))*.

Moreover, the claiming of human "recognition" seems to run afoul of several well-established principles of patent law.

First, allowing ICN to claim the "recognition" of an inherent property would read out the meaning of the Federal Circuit's decisions in *Cruciferous Sprout* n20 and *Atlas Powder*. n21 Under ICN's arguments, had the patentee in Cruciferous Sprout added a limitation of "recognizing that certain cruciferous sprouts had properties that reduced the level of carcinogens" and the patentee in Atlas Powder added a method claim with a limitation of "recognizing the aeration property," then the Federal Circuit would have held the claims valid and not anticipated. Such a result seems unintended.

> n20 In Cruciferous Sprout, the patentee claimed a method of preparing a food product rich in glucosinolates and attempted to claim the newly discovered fact that certain cruciferous sprouts had properties that lowered the level of carcinogens in animals, thereby reducing the risk of developing cancer. The district court found that prior to the issuance of the patent, one skilled in the art could, by following the teachings of the prior art, practice the claimed method and held the claims invalid as anticipated. On appeal, the Federal Circuit affirmed the district court's conclusion that the patentee had "done nothing more than recognize properties inherent in certain prior art sprouts. . . [and that while the patentee] may have recognized something quite interesting about those sprouts, it simply [had] not invented anything new." *Cruciferous Sprout, 301 F.3d at 1350-51*. **[*61]**

> n21 In Atlas Powder, the patentee claimed a blasting composition including a newly discovered "aeration" property that tiny air bubbles existed within the composition which, upon detonation, enhanced the explosion. The district court held the patent invalid over prior art that disclosed blasting compositions with the same ingredients, even though they did not disclose the aeration property because the aeration property was an inherent element in the prior art blasting compositions. The Federal Circuit affirmed the district court finding that there was no clear error in the district court's conclusion that the aeration property was inherent in the prior art reference. In addition, the Federal Circuit stated that "because [the aeration property] was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the invention]." *Atlas Powder, 190 F.3d at 1348*.

Second, once physicians learned of ICN's "invention," ICN could stop physicians from practicing what even ICN admits is the prior art because the

physicians could not then turn [*62] "off" such recognition; to avoid infringement, the physicians would have to stop practicing what has long been in the prior art (e.g., administering ribavirin in prior art dosages of 800 mg/day).

Third, allowing cognitive limitations directed towards subjective human realization rewards ignorance rather than the patent statute's goal of promoting the progress of science and useful arts. See *U.S. Const. art. I, § 8, cl. 8*. Physicians might be wary of learning about new advances for fear of infringing patent claims with "cognitive" limitations. By remaining ignorant of new developments, physicians could steer clear of potential infringement allegations.

Fourth, allowing a party to include a cognitive element in a claim gives the patentee rights beyond those contemplated by the patent statutes. An issued patent does not give the patentee any affirmative rights, but instead, gives the patentee the ability to "exclude others from making, using, offering for sale, or selling the invention throughout the United States." *35 U.S.C. § 154(a)(1)*. To allow cognitive elements directed to subjective human recognition would grant the patentee the ability to preclude [*63] others from exercising their own cognitive functions. n22

n22 Furthermore, while ICN's claims includes both cognitive and administration elements, under ICN's logic, a claim that merely claimed only a cognitive element would be equally patentable, providing it met the other requirements of patentability. In this case, for example, the patent claim could be solely directed at subjective human realization wherein the ICN could preclude physicians from consciously realizing the effects of ribavirin.

Thus, the Court sees obvious problems with ICN's validity arguments. Despite these reservations, however, the Court does not believe that further briefing, argument, and discussion of the validity issues is warranted in light of the granting of summary judgment of non-infringement in all three cases.

IT IS SO ORDERED

DATED: July 14, 2003

Honorable Mariana R. Pfaelzer

United States District Judge.